

REMARKS

I. Status of the Application

Claims 1, 2, 5-14, 21 and 24-35 are pending in the application. Applicants gratefully acknowledge the Examiner's withdrawal of the rejections of claims 29-32 under 35 U.S.C. § 112, second paragraph; claims 8 and 26 under 35 U.S.C. § 112, first paragraph; claims 1, 2, 5-14, 21, 24-29 and 31-35 under 35 U.S.C. § 103(a) over Pirhonen et al. in view of Santos et al.; and claim 30 under 35 U.S.C. § 103(a) over Pirhonen et al. in view of Santos et al. and further in view of Hall.

Claims 1, 7-10 and 25-35 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 4 and 14 of copending US patent application no. 10/354,856. Claims 10-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 1, 2, 5, 6, 21 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dieter et al. (US Patent 5,434,919). Claim 13 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Rolle et al. (US Patent 6,969,303). Claims 1, 7-10 and 25-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Weber (US 2004/0152627). Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. (US Patent 6,180,606) in view of Weber (US 2004/0152627).

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, claim 1 has been amended to include the subject matter of dependent claim 11, and claim 11 has accordingly been canceled. Support for this amendment can be found at page 10, paragraph 49 of the specification, which discloses a carrier that can be a composite material comprising a ceramic part and a polymer part. Claim 12 has been amended to correct dependency. Claims 7-9 and 25-27 have been cancelled. New claim 36

has been added to claim an implant coated with a bone grafting material. Support for this amendment can be found at pages 11 and 12, paragraph [0054] of the specification. Page 12, paragraphs [0055]-[0061] also describe coated implants and methods for coating.

Applicants respectfully submit that the amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

II. Interview Summary

On June 12, 2006, Applicants' representative telephoned the Examiner to inquire as to the extent of evidence necessary to establish a joint research agreement. The Examiner stated that an affirmative statement of the existence of such an agreement, and amendment of the specification to disclose the names of the parties in the agreement, are sufficient to establish a joint research agreement under 35 U.S.C. § 103(c).

III. Double Patenting

At page 3, paragraph 8 of the instant Office Action, claims 1, 7-10 and 25-35 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 4 and 14 of copending US Patent Application No. 10/354,856 to Weber. Applicants respectfully traverse the rejection based on the amended claims. Claims 7-9 and 25-27 have been cancelled in the present amendment, thus rendering moot the rejection against them.

The Examiner is of the opinion that the subject claims are not patentably distinct from the claims of Weber because the subject claims are a species of the genus claimed by Weber. Applicants respectfully disagree. The MPEP at section 806.04(d) defines the relationship between a generic claim and a species claim as: “a generic claim should require no material element *additional* to those required by the species claims, and each of the species claims must require *all* the limitations of the generic claim.” (Emphasis added.) Claims 1, 4, and 14 of Weber all recite a bone morphogenetic protein as the first element of its claimed composition. Since claims 7-9 and 25-27 have been cancelled, none of the remaining subject claims recites bone morphogenetic protein, or even a class of bioactive agent including bone morphogenetic protein. Thus, claims 1, 10, and 28-35 of the present application are not a species of the Weber claims, because the Weber claims require an additional element not required by the subject claims. Therefore, the subject claims are directed to an invention that is patentably distinct from that of claims 1, 4, and 14 of Weber. Accordingly, Applicants respectfully request withdrawal of the provisional obviousness-type double patenting rejection and allowance of claims 1, 10, and 28-35.

IV. Claims 10-12 Are Definite

At page 4, paragraph 10 of the instant Office Action, claims 10-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner is of the opinion that the limitations of claims 10 and 11 do not have antecedent basis in claim 1. Claim 12 is rejected for depending on rejected claim 11. Applicants respectfully traverse the rejection.

The Examiner asserts that the limitations of “carrier selected from the group consisting of calcium phosphates, hydroxy apatites, silica gels, anorganic mineral bone matrixes, xerogels and sol-gel glasses” recited in claim 10 are not encompassed by the limitations of “porous carrier of ceramic or glass ceramic or glass” recited in claim 1. Applicants respectfully disagree based on the specification disclosure. Page 4, paragraph [0017] of the specification defines calcium phosphates and hydroxyapatites as ceramics. Page 7, paragraph [0040] discloses glass based on silica and prepared by a sol-gel process. Page 9, paragraph [0045] defines anorganic mineral bone matrix as a bioceramic, which is understood by the skilled artisan as a sub-category of ceramic. Page 7, paragraph [0039] defines xerogel as glass. Page 7, paragraph [0035] defines sol-gel as a method for making porous carriers, specifically ceramics. In claim 10, sol-gel is recited as a type of glass. Therefore, all of the limitations recited in claim 10 fall into the categories of “ceramic or glass ceramic or glass” recited in claim 1.

The Examiner asserts that the “ceramic/polymer composite” limitation recited in claim 11 does not have antecedent basis in the carrier of claim 1. Applicants have amended the subject matter of claim 11 into claim 1 and canceled claim 11, so the rejection is now moot. Claim 12 has been amended to depend correctly from claim 1. For the reasons given above, claims 10 and 12 do particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, second paragraph, rejection and allowance of claims 10 and 12.

V. Claims 1, 2, 5, 6, 21 and 24 Are Novel over Dieter

At page 5, paragraph 15 of the instant Office Action, claims 1, 2, 5, 6, 21 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dieter et al. (US Patent 5,423, 919)

(“Dieter”). The Examiner is of the opinion that the composition disclosed by Dieter encompasses the limitations of the pending claims and therefore anticipates the claims. Applicants respectfully traverse the rejection.

The Examiner asserts that the preambles of the subject claims are not claim limitations and are of no significance to claim construction. However, if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or if the claim preamble is “necessary to give life, meaning, and vitality” to the claim, then the claim preamble should be construed as if in the balance of the claim. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

Applicants submit that the preambles “a bone grafting material” and “an implant” are necessary to give life, meaning and vitality to independent claim 1 and independent claim 21, respectively, because they serve to further define the structure of the material. For example, a preamble reciting “an abrasive article” was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder, because it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an “abrasive article.” Therefore, the preamble served to further define the structure of the article produced. *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Similarly, it is only by the preamble that it can be known that the subject matter defined by the present claims is comprised as a “bone grafting material” and an “implant.” Every union of porous carrier and pyrrolidone is not a “bone grafting material” or an “implant.” The cleaning composition disclosed by Dieter is certainly inoperable as a bone grafting material or an implant. Apart from ceramic particulate and N-methyl-2-pyrrolidone, Dieter’s cleaning

composition also requires a liquid organic solvent in an amount of 80-99 % by weight of the composition (abstract, col. 4, lines 37-43). Such a large amount of organic solvent renders Dieter's composition not bio-compatible, so Dieter's composition would be harmful to human or animal if implanted and/or used as a bone grafting material. The Federal Circuit has ruled that if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Since Dieter's cleaning composition is not capable of performing as a bone grafting material or as an implant, it fails to disclose the invention defined by the claims.

Therefore, Dieter fails to anticipate independent claims 1 and 21. For at least the same reasons, dependent claims 2, 5, 6, and 24 are also novel over Dieter. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection and allowance of claims 1, 2, 5, 6, 21 and 24.

VI. Claim 13 Is Novel over Rolle

At page 6, paragraph 16 of the instant Office Action, claim 13 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Rolle et al. (US Patent 6,969,303) ("Rolle"). The Examiner is of the opinion that Rolle teaches each and every claim limitation. Applicants respectfully traverse the rejection

Claim 13 is directed to a bone grafting material comprising a porous carrier including calcium phosphate and 1-methyl-2-pyrrolidone (NMP). The Examiner asserts that Rolle teaches an aromatic hydrocarbon, and NMP can reasonably be interpreted to be an aromatic hydrocarbon, so Rolle teaches NMP. Applicants respectfully disagree. The skilled artisan would recognize that NMP has only one double bond (the carbonyl), so NMP does not have a

conjugated ring system as required in an aromatic hydrocarbon. Nor does NMP fall into any other category of solvent disclosed by Rolle (col. 4, lines 39-46). The Examiner may wish to argue that NMP is an aliphatic hydrocarbon, but this is not the case. Aliphatic hydrocarbons are open-chain, such as Rolle's examples of hexane and heptane at col. 4, lines 39-40. NMP is a ring, so NMP is not aliphatic. For the above reasons, Rolle fails to teach NMP.

Rolle does not anticipate claim 13 because Rolle fails to teach each and every claim limitation. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(e) rejection and allowance of claim 13.

VII. Claims 1, 10 and 28-35 Are Patentable over Weber

At page 6, paragraph 17 of the instant Office Action, claims 1, 7-10 and 25-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Weber (US 2004/0152627). The Examiner is of the opinion that the claimed invention is obvious in view of Weber. Applicants respectfully traverse the rejection based on 35 U.S.C. § 103(c). Claims 7-9 and 25-27 have been cancelled in the present amendment, thus rendering moot the rejection against them.

35 U.S.C. § 103

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if –

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term “joint research agreement” means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

Weber qualifies as prior art under 35 U.S.C. § 102(e). Weber is assigned to the University of Zurich. The claimed invention of the present application, with inventors Eija Pirhonen, Loredana Moimas, and Franz Weber, is assigned to Inion, Ltd. The claimed invention was made by or on behalf of the University of Zurich and Inion, Ltd., who are parties to a joint research agreement. The agreement came into effect on February 17, 2003, which is before the date the claimed invention was made. The joint research agreement is in the field of bioactive materials for bone formation and the claimed invention was made as a result of activities undertaken within the scope the agreement. The specification has been amended in this response in accordance with 37 C.F.R. § 1.71(g) to disclose the names of the parties to the joint research agreement. Therefore, all the requirements of 35 U.S.C. § 103(c) have been met, so Weber shall not preclude patentability. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claims 1, 10 and 28-35.

VIII. Claim 14 Is Patentable over Chen in View of Weber

At page 8, paragraph 18 of the instant Office Action, claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. (US Patent 6,180,606) (“Chen”) in view of Weber (US 2004/0152627). The Examiner is of the opinion that claim 14 is obvious over the combined teachings of Chen and Weber. Applicants respectfully traverse the rejection.

Claim 14 is directed to a bone grafting material comprising a porous carrier including calcium phosphate, 1-methyl-2-pyrrolidone (NMP) and at least one bone morphogenetic protein

(BMP). The Examiner admits that Chen does not disclose a composition comprising a pyrrolidone. Chen in no way suggests the desirability of including pyrrolidones in his osteogenic composition. The Examiner relies on Weber for disclosure of pyrrolidones, and for motivation to combine pyrrolidones with Chen's composition. According to the provisions of 35 U.S.C. § 103(c), Weber has been disqualified as prior art under 35 U.S.C. § 103(a), as shown above in section VII. For this reason, Applicants respectfully submit that the combination of Weber with Chen is improper. Since Chen alone fails to teach or suggest all the claim limitations and also fails to provide motivation to modify the reference, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of claim 14.

IX. Conclusion

Having addressed all outstanding issues, Applicants respectfully request reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

In compliance with 37 C.F.R. § 1.71(g), the Commissioner is authorized to apply the fee of \$130.00 required under 37 C.F.R. § 1.17(i), and any additional charges or credits to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: August 15, 2006



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